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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/312,485	05/17/99	DEBREGEAS	P 065691/0163

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EXAMINER
SHARAREH, S

ART UNIT	PAPER NUMBER
1619	6

DATE MAILED: 10/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/312,485

Applicant(s)

Debregeas et al

Examiner
Shahnam Sharar h

Group Art Unit
1619



☒ Responsive to communication(s) filed on May 17, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-20 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-20 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1619

DETAILED ACTION

Claims 1-20 are pending

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-9 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 1-20 are indefinite. The instant claims are rendered indefinite by the phrases “characterized in that” or “characterized in that they comprise” because it is not readily apparent what the applicant intends by said phrases. The examiner of record suggests the use of phrases “comprising”, “consisting essentially of”, or “consisting of” as an alternative in Claims ; and “wherein” in Claims. The metes and bounds of the claims are not clear.

4. Claim 2 is rejected because of the improper Markush-type claims. Applicant is advised to use proper Markush-type claim so that the metes and bounds of the claim becomes clear. As an example, a claim may be drawn to a composition comprising A, and B, wherein B is selected from the group consisting of C, D, E and F.

5. Claims 6-8, 16-17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite, because of the use of trademark in the claims. The scope of the claims are uncertain as regards the

Art Unit: 1619

material which forms the "Aquacoat", "Eudragit NE", "Neutres". The use of trademark in claims renders the instant claim indefinite.

6. Regarding claim 4, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

7. Regarding claim 14, the phrase "30-40%" renders the claim indefinite because it is unclear what is the type of percentage of alcohol (weight, vol, etc..) See MPEP § 2173.05(d).

8. Regarding claim ⁴⁵~~14~~¹⁰, the recitation of "0.1 mg/g or 750 mg/g" renders the claim indefinite because it is unclear what ratio mg/g represents, mg/g of what? See MPEP § 2173.05(d).

9. Claim 11 rejected as being indefinite and vague. It appears that the instant claim missing an essential step of selecting a neutral core and/or combining with a pharmaceutically acceptable excipient.

10. Claims 16-17 recites the limitation "Neutres". There is insufficient antecedent basis for this limitation in the claim. Further, it is not clear what is meant by the term Neutres. Neutres is not an art recognized term and the specification does not provide any guidance to describe what Neutres is.

Priority

11. Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon an application FR 99 03075 filed on March 12, 1999.

Art Unit: 1619

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

12. Claims 1, 5, 9, 11-12 rejected under 35 U.S.C. 102(b) as being anticipated by WO 9704861 ("861").

The instant methods are directed to granules comprising a plant substance, at least one, and a process of making said granules.

'861 disclose production of solid granules comprising an active core comprising an herbal moiety, and at least one layer of coating, *abstract*. Thus, '861 meets the limitations set forth in the instant claims.

13. Claims 1-15 rejected under 35 U.S.C. 102(b) as being anticipated by Jacob et al US Patent 5,733,551.

Jacob et al disclose process of preparing herbal compositions comprising selecting a herbal extract containing a plant material produced, dissolving it in an organic solvent such as an alcohol in concentrations of at least 30% weight, adding a cellulose or other natural polymers, granulating, extruding the mixture and finally obtaining an herbal containing composition. *Col. 3 lines 6-30, Example 1-2, col. 8 lines 16-59, col 9 lines 35-36*. Jacob disclose adding various

Art Unit: 1619

auxiliary compounds such as lactose, polyvinyl pyrrolidone, sorbitol or lactose, in suitable concentrations to their final product to prepare an oral herbal composition that can provide rapid or gradual release of the active ingredient. *Col. 2 lines 59-67, col 3. lines 20-24, col. 10 lines 1-35.* Therefore, Jacob et al meet the limitations set forth in the instant claims.

14. Claims 1-3, 9-15 rejected under 35 U.S.C. 102(e) as being anticipated by De Long et al US Patent 6,030,621.

De Long et al disclose processing Ginkgo biloba leaves by dissolving the Ginkgo biloba leaves into an organic solvent to produce an extract and a residue, and then separating the extract from the residue and concentrating it for medicinal use, *col 8 lines 1-20.* De Long further teach preparing Ginkgo pharmaceutical compositions in the form of granules comprising sucrose, starch, and hydroxypropyl cellulose, *col 19 lines 60-67, col 20 lines 1-5.* Thus, De Long et al meet the limitations set forth in the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Long et al US patent 6,030,621 in view of Breitenbach et al US Patent 6,120,802.

The teachings of De Long et al are discussed above. De Long et al do not specifically teach various controlled release coated formulations of Ginkgo biloba.

Art Unit: 1619

Breitenbach et al teach methods of formulating controlled release formulations of various types of pharmaceutically active agents such as herbal substances including Ginkgo biloba having multilayers of coating, *col 5 line 65*. Breitenbach specifically teach the use of various conventional additives including plasticizer and binders such as hydroxypropylcellulose, polyvinyl pyrrolidone, acrylic acid copolymers to formulate their multi layer compositions, *col 9 lines 1-37*. Breitenbach et al also teaches conventional methods of coating by treating their formulation in a coating pan or fluidized bed apparatus, *col 7 lines 29-30*.

Both De Long and Breitenbach teach methods of preparing solid oral dosage formulations, thus their teachings are viewed to be in the same field of endeavor.

Although De Long et al do not specifically disclose a multi layer controlled release comprising an herbal substance, it would have been obvious to one of ordinary skill in the art of drug dosage forms at the time of invention to incorporate the plasticizer and binders taught by Breitenbach into De Long's Ginkgo biloba (a plant substance) granules, and then apply coating on them by conventional methods known in the art, to formulate a multi layer controlled release formulation of Ginkgo biloba granules that possesses better pharmacokinetics properties, and moreover improves patients compliance.


Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnaz Sharareh, PharmD whose telephone number is (703) 306-5400. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are

Art Unit: 1619

unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone number for this Group is 703-308-4556. Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-1235.

ss 10/5/2000



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